

**HEARTGARD- ivermectin tablet, chewable**  
**Merial, Inc.**

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**Heartgard®**  
**(ivermectin)**

**Chewables for Cats**

**Caution**

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

**INDICATION**

For use in cats to prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection, and for the removal and control of adult and immature hookworms (*Ancylostoma tubaeforme* and *A. braziliense*).

**DOSAGE**

HEARTGARD for Cats should be administered orally at monthly intervals at the recommended minimum dose level of 24 mcg of ivermectin per kg (10.9 mcg/lb) of body weight. The recommended dosage schedule for prevention of feline heartworm disease and control of hookworm is as follows:

<b>Cat Weight lb</b>	<b>HEARTGARD for Cats Chewables per Month</b>	<b>Ivermectin content</b>
Up to 5 lb	1	55 mcg
5 to 15 lb	1	165 mcg

For cats over 15 lb, use the appropriate combination of chewables.

HEARTGARD for Cats is recommended for use in cats 6 weeks of age and older.

**ADMINISTRATION**

Remove only one chewable at a time from the foil-backed blister card. Return the card with the remaining chewables to its box to protect the product from light. HEARTGARD for Cats can be offered to the cat by hand or may be added to a small amount of cat food. If manual dosing is required, the chewable should be broken into pieces for administration. Food should be routinely available during the day of treatment administration. If cats are fasted, or if the chewable is not broken into pieces for manual dosing, then reduced absorption may result. A relationship between reduced absorption and reduced efficacy has not been established.

Care should be taken to see that the cat consumes the complete dose. Treated animals should be observed for a few minutes after administration to ensure that part of the dose is not lost or rejected. If it is suspected that any of the dose has been lost, redosing with a new chewable is recommended. Fragments of chewables have occasionally been observed in the feces of some cats; efficacy of the product was not adversely affected.

HEARTGARD for Cats should be given at monthly intervals when mosquitoes potentially carrying infective heartworm larvae are active. The initial dose must be given within a month (30 days) after the cat's first exposure to mosquitoes. The final dose must be given within a month (30 days) after the cat's last exposure to mosquitoes. For optimal performance, HEARTGARD for Cats must be given once a

month on or about the same date. If treatment is delayed, whether by a few days or many, immediate treatment with HEARTGARD for Cats and resumption of the recommended dosing regimen will minimize the opportunity for development of adult heartworm.

It is recommended that cats should be tested for existing heartworm infection prior to starting treatment with HEARTGARD for Cats. Cats already infected with adult heartworms can be given HEARTGARD for Cats monthly to prevent further infections.

Monthly treatment with HEARTGARD® (ivermectin) for Cats also provides effective removal and control of adult and immature hookworms (*A. tubaeforme* and *A. braziliense*).

## **SAFETY**

In the clinical studies involving more than 3000 doses of HEARTGARD for Cats, observations reported within 24 hours of treatment included vomiting in  $\leq 0.3\%$  and diarrhea in  $\leq 0.2\%$  of the doses administered. There were no statistical differences between HEARTGARD for Cats and the product vehicle (control) for these observations.

A wide margin of safety was demonstrated in clinical trials at the recommended dose level in cats and kittens 6 weeks of age and older and in laboratory studies in cats with circulating microfilariae of *D. immitis*. A wide margin of safety has also been demonstrated at 3 times the recommended dose in pregnant or breeding queens and breeding toms. No adverse effects were observed in either male or female cats or their offspring in breeding studies. A 30-fold safety margin over the minimum recommended dosage was established in a single dose tolerance study. In growing kittens dosed monthly for 8 consecutive doses, one cat given 5 times the market dose vomited and a second cat in this group experienced diarrhea within 24 hours of the initial treatment. In clinical trials, many commonly used flea control products, anthelmintics, vaccines, antibiotics and steroid preparations were administered with HEARTGARD for Cats without incident.

**Keep this and all drugs out of the reach of children.** In case of ingestion by humans, clients should be advised to contact a physician immediately.

## **STABILITY**

HEARTGARD Chewables for Cats are stable for 3 years when stored below 77°F (25°C) and protected from light. Store at controlled room temperature of 68°F-77°F (20°C-25°C). Excursions between 59°F-86°F (15°C-30°C) are permitted.

## **HOW SUPPLIED**

HEARTGARD for Cats is available in two dosage strengths (see DOSAGE section) for cats of different weights. Each strength comes in a convenient carton of 6 chewables, packed 10 cartons per tray.

For customer assistance, please contact Merial at 1-888-637-4251.

Marketed by  
Merial, Inc.  
3239 Satellite Blvd.  
Duluth, GA 30096  
Made in USA

Merial is the Animal Health Division of sanofi.

NADA 141-078, Approved by the FDA.

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Rev. 05-2015

1050-2169-05

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**PRINCIPAL DISPLAY PANEL - 55 mcg Tablet Blister Pack Carton**

***Heartgard***<sup>®</sup>  
(ivermectin)

**Chewables  
for Cats**

**Administer once a month to prevent  
heartworm disease and to remove and  
control infections of hookworms in cats.**

***For  
CATS  
UP TO 5 lbs***

**6 Chewables**  
Each chewable contains 55 mcg of ivermectin.

**Keep this and all drugs out  
of the reach of children.**

**Caution:** Federal (U.S.A.) law restricts  
this drug to use by or on the order of  
a licensed veterinarian.

**MERIAL**

Product 38055  
1030-2603-04

**Heartgard**<sup>®</sup>  
(ivermectin) Chewables for Cats

▼ Lot & Exp

**6** Chewables For CATS  
UP TO 5 lbs

**Heartgard**<sup>®</sup>  
(ivermectin) Chewables for Cats

**6** Chewables  
For CATS  
UP TO 5 lbs

# Heartgard<sup>®</sup>

(ivermectin) Chewables for Cats

Administer once a month to prevent heartworm disease and to remove and control infections of hookworms in cats.

For  
**CATS**  
UP TO 5 lbs



**6** Chewables

Each chewable contains 55 mcg of ivermectin.



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**Caution:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.



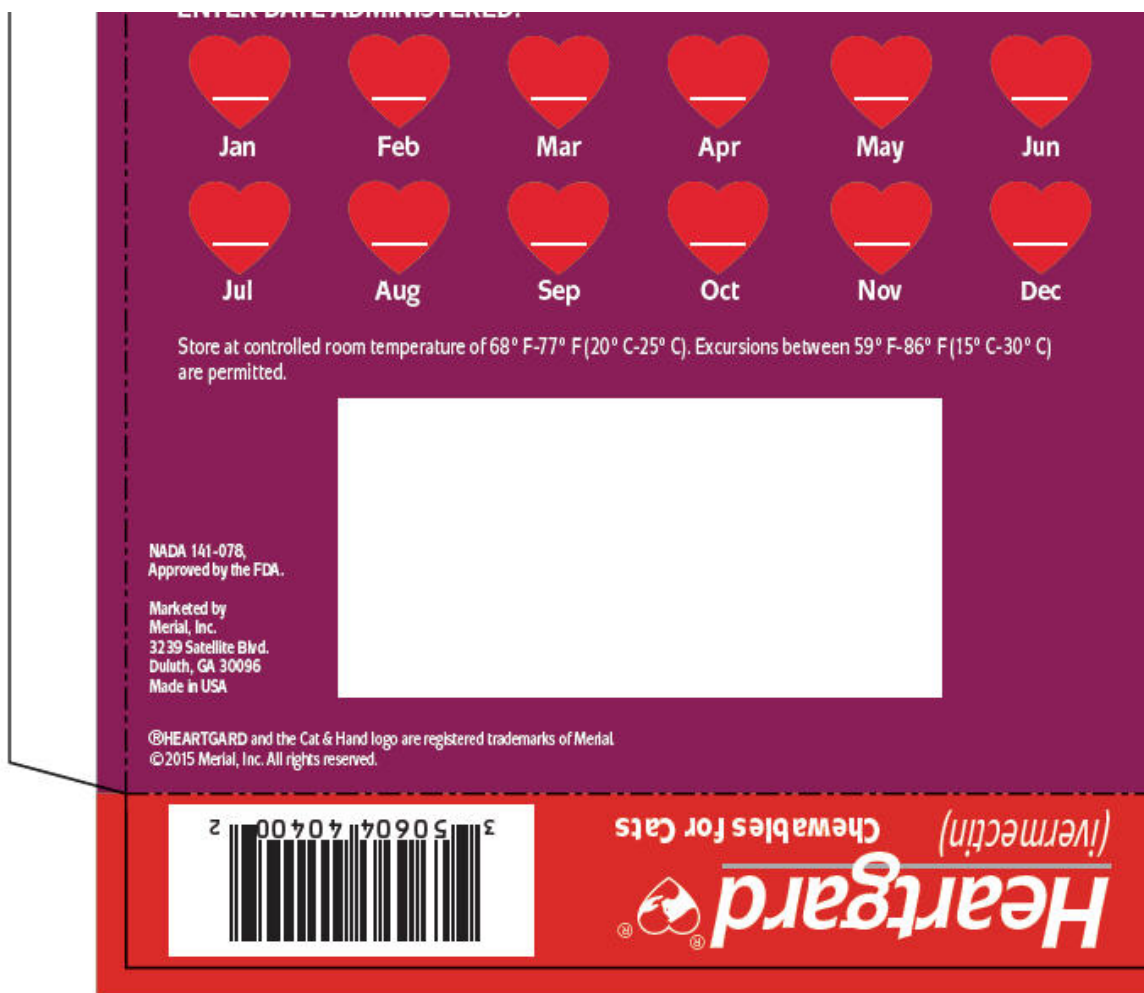
For CATS  
UP TO 5 lbs  
**6** Chewables

**Heartgard**<sup>®</sup>  
(ivermectin) Chewables for Cats



1030260304

ENTER DATE ADMINISTERED:



## PRINCIPAL DISPLAY PANEL - 165 mcg Tablet Blister Pack Carton

**Heartgard®**  
(ivermectin)

**Chewables  
for Cats**

**Administer once a month to prevent  
heartworm disease and to remove and  
control infections of hookworms in cats.**

**For  
CATS  
5 TO 15 lbs**

**6 Chewables**

Each chewable contains 165 mcg of ivermectin.

**Keep this and all drugs out  
of the reach of children.**

**Caution:** Federal (U.S.A.) law restricts  
this drug to use by or on the order of  
a licensed veterinarian.

**MERIAL**

Product 38165  
1030-2605-04

**Heartgard**®

(ivermectin)

Chewables for Cats

**6**

Chewables

For CATS  
5-15 lbs

▼ Lot & Exp

**Heartgard**®  
(ivermectin)  
Chewables for Cats

**6** Chewables

For CATS  
5-15 lbs

# Heartgard®

(ivermectin)



Chewables  
for Cats

Administer once a month to prevent heartworm disease and to remove and control infections of hookworms in cats.

For  
CATS  
5 TO 15 lbs



**6** Chewables

Each chewable contains 165 mcg of ivermectin.



Keep this and all drugs out of the reach of children.

Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.



For CATS  
5-15 lbs  
**6** Chewables

**Heartgard**®  
(ivermectin)  
Chewables for Cats



1030260504

ENTER DATE ADMINISTERED:





## HEARTGARD

ivermectin tablet, chewable

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:50604-4040
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	55 ug

### Product Characteristics

<b>Color</b>	RED (red to red-brown)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50604-4040-1	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
2	NDC:50604-4040-3	1 in 1 CARTON		
2		1 in 1 BLISTER PACK		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA		NADA141078	12/23/1996	

HEARTGARD				
ivermectin tablet, chewable				
Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:50604-4041	
Route of Administration	ORAL	DEA Schedule		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)		ivermectin	165 ug	
Product Characteristics				
Color	RED (red to red-brown)	Score	no score	
Shape	ROUND	Size	14mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50604-4041-1	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA141078	12/23/1996		

Labeler - Merial, Inc. (799641006)



